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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,102	07/31/2001	Howard Fein	HOFE / 02	2446
26875	7590	12/10/2004	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			WITZ, JEAN C	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,102

Applicant(s)

FEIN, HOWARD

Examiner

Jean C. Witz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2 and 4-53 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,11-23,26-29,32,33,41,42 and 44-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8-10, 24-25, 30-31, 34-40 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant requests that the Examiner reinstate claims 26-28, 32-33 and 41 (currently withdrawn as being drawn to a non-elected species). Applicant argues that claims 26-28 parallel claims 24-25, currently under examination. Applicant also argues that claims 32-33 encompass an embodiment of claims 24-25 and that claim 41 depends from claim 34. Applicant's arguments are not persuasive and claims 26-28, 32-33 and 41 are still withdrawn from consideration. Claims 24-25 recite that the method selectively removes "at least one epidermal layer". Claims 26-27 recite that the protease acts to "selectively remove at least one dermal layer". Claim 41 addresses the treatment of the dermal layer. The epidermis and the dermis are two completely different layers of the skin. They comprise totally different tissues and cell types. The epidermis is comprised of layers of epithelial cells. Removal of epidermal layers, in the least, occurs normally and daily when clothes and other surfaces brush across or rub the skin surface. The dermis is found internal to the epidermis and is composed mainly of connective tissue. Removal of the dermis usually results in extreme trauma, such is the case with third degree burns. Therefore, the two methods are clearly distinct from each other. Further, the elected condition species, seborrheic keratosis, is a condition of the epidermis and not of the dermis. Therefore, these claims recite a non-elected species and are properly withdrawn from consideration. With regard to claim 28, the protease is limited to collagenases, elastases or combinations thereof. Trypsin, the elected enzyme species, is neither a collagenase nor an elastase. Therefore, claim 28

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recites a non-elected species and is properly withdrawn from consideration. Claims 32-33 recite the treatment of aging. The elected condition species was the treatment of seborrheic keratosis, which is distinct from the condition of aging. Therefore, claims 32-33 recite a non-elected species and properly withdrawn from consideration.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2, 4-5, 9-10, 24-25, 30-31, and 34-40 are rejected under 35

U.S.C. 102(b) as being clearly anticipated by SU 1685448.

2. Claims 1-2, 4-5, 9-10, 24-25, 30-31, and 34-37, 39-40 are rejected under 35

U.S.C. 102(b) as being clearly anticipated by U.S. Patent to de Faire et al. (6,030,612).

With regard to Applicant's contention that the Examiner has not complied with the duty to point out relevant sections of the references, per MPEP 7.06.02(i), the term "clearly anticipates" is properly used in the rejection. When the references are explicit on their face that they meet each and every limitation of the claims, no further explanation is necessary. While the MPEP does state "Note that the particular part of the reference relied upon to support the rejection should be identified", in both cases, the parts of the references that supported the rejection were clear and unmistakable, as evidenced by the fact that Applicant correctly addressed the asserted anticipatory teachings in the response. Therefore, based upon that argument alone, this office action may be properly made final.

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With regard to Applicant's arguments about the SU 1685448 reference, Applicant asserts that the use of the phrase "consisting essentially of" "require the enzyme is sole active ingredient." Applicant's interpretation of the phrase "consisting essentially of" is inconsistent with accepted current patent law. Per the MPEP at 2111.03, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In *re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the

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invention."). Applicant states, at page 18 of the specification, that "[t]he composition containing an enzyme or mixture of enzymes may also contain other compounds that have desirable therapeutic, cosmetic, and/or aesthetic properties, that either do not affect or only minimally affect the activity of the enzyme." If an applicant contends that additional materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant's invention. In *re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). It is clear that the composition of SU 1685448 has other ingredients but it is equally clear, since the composition is taught to be effective for the treatment of seborrheic keratosis, that the other ingredients meet the requirements set forth by Applicant, i.e. "do not affect or only minimally affect the activity of the enzyme", but this is not the same as the requirements of the patent law, i.e. that the non-claimed but disclosed ingredients "do not materially affect the basic and novel characteristic(s)" of the claimed invention. As long as the disclosed, but non-claimed, ingredients in the prior art do not affect the characteristics of the claimed ingredient, then the claim is open to those ingredients. This is Applicant's burden and one that has not been met on the record. Therefore, Applicant's arguments are not probative and not persuasive.

With regard to Applicant's arguments regarding the rejection over the U.S. Patent to de Faire et al. (6,030,612), Applicant asserts that the use of the multifunctional enzyme cannot be selective and that each of Applicant's claims requires selective treatment. However, this interpretation of the claim is far too narrow and not supported

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by the claim language. The term "selective" is used in the phrase "selective for a layer of skin" and modifies the phrase "at least one hydrolase". Therefore, more than one enzyme may be present in the composition used in the claimed method and there is no limitation in the claim that requires that all hydrolases be selective for the same layer of skin. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, 4-5, 9-10, 24-25, 30-31, and 34-40 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent Application Publication to Freeman (Pub. No. US 2003/0021775).

Applicant argues that the published application neither anticipates nor renders obvious Applicant's invention. Applicant argues that the reference requires pressurized fluid for hydrostatic tissue debridement and that there is no teaching, suggestion, or motivation to provide non-pressurized formulation. As addressed supra, in response to

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applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim limitations are broad enough that broadest reasonable interpretation of the term "treatment" encompasses both pressurized and non-pressurized treatment. Therefore, Applicant's arguments are not probative and not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

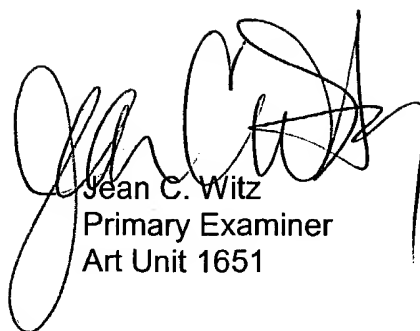
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Sean C. Witz
Primary Examiner
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